State of California—Health and Human Services Agency

CLEAR FORM

Department of Health Services
Food and Drug Branch

NEW MEDICAL DEVICE MANUFACTURING LICENSE APPLICATION

PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED

See page 2 for instructions.

☐ NEW APPLICANT ☐ RELOCATION ☐ OWNERSHIP CHANGE ☐ OWNERSHIP AND LOCATION CHANGE

1. Name of Firm			9. Facility Operator (name and title)		
2. DBA (List additional DBA's on separate sheet if necessary.)			10. Facility Telephone Number ( )	11. Facility FAX Number ( )	
3. Facility Address (number, street)			12. 24-Hour Emergency Telephone Number ( )	13. E-mail Address	
4. Facility Address (continued)			14. Correspondent (name and title)		
5. City	State	ZIP Code	15. Correspondent Telephone Number ( )	16. Correspondent FAX Number ( )	
6. Mailing Address (if different from firm or P.O. Box number)			17. Country (if other than United States)	18. FDA CFN or FEI Number	
7. Mailing Address (continued)			19. Web site (URL)		
8. City	State	ZIP Code	20. Interstate Commerce ☐ Product Shipped ☐ Product or Raw Materials Received ☐ N/A		

21. Type of Ownership
☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation/Limited Liability Company ☐ Nonprofit ☐ Other:_____

22. Corporate Name (if applicable)	State of Incorporation
23. Owners' or Officers' Names and Titles	Owners' or Officers' Names and Titles

24. Type of Manufacturing Business (check all that apply)
☐ Manufacturer ☐ Contract ☐ Component ☐ Specification Developer ☐ Other: _____

25. Stage of Manufacture at Date of Application (check all that apply)
☐ Manufacturing Products ☐ Design Development ☐ Design Validation ☐ Pre-production Design Transfer ☐ Other: _____

26. Intended Device Destination (check all that apply)
☐ Investigational Studies ☐ Export Market ☐ California Distribution ☐ U.S. Distribution ☐ Other: _____

27. Check Each Product Area that Applies to the Devices Manufactured

☐ 862 Clinical Chemistry and Clinical Toxicology	☐ 874 Ear, Nose, and Throat	☐ 886 Ophthalmic
☐ 864 Hematology and Pathology	☐ 876 Gastroenterology/Urology	☐ 888 Orthopedic
☐ 866 Immunology and Microbiology	☐ 878 General and Plastic Surgery	☐ 890 Physical Medicine
☐ 868 Anesthesiology	☐ 880 General Hospital and Personal Use	☐ 892 Radiology
☐ 870 Cardiovascular	☐ 882 Neurological	☐ Unclassified Devices
☐ 872 Dental	☐ 884 Obstetrical and Gynecological	

28. List the types of classified and/or unclassified manufactured devices in the spaces below. Use additional sheets if necessary.

Federal Classification Title	Classification (Check One) I	II	III

29. Identify processes employed or planned in the manufacture of the devices listed above and if activities will be done in-house or by contract. Use additional sheets if necessary.

Process/Activities	In-House	Contract	Process/Activities	In-House	Contract
Sterilization			Repackaging/Relabeling		
Software Development			Remanufacturing/Refurbishing		
Circuit Board Assembly			Tissue/Cell Culture		
Lyophilization			Other:		
Antigen/Antibodies					

30. Payment Codes (Check only one code—see page 2, sec. 30)
☐ **A—$1600** ☐ **B—$850**

31. **License Fees Due:** **Enter Fee Below:**
a. License Fee (see #30) **$**
b. **Total Payment Due** **$**

The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by California Health and Safety Code §111630. By signature, I declare under penalty of perjury that all information provided herein is true and correct.

32. Signature of Applicant	Printed name	Title	Date

PLEASE DO NOT WRITE BELOW THIS LINE.

License Number	Expiration Date	Date Received	Payment Type	Amount
				$

New Medical Device Manufacturing License Application Instructions

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application as indicated in the fee schedule and make payable to: DEPARTMENT OF HEALTH SERVICES. This fee must accompany this application or the application cannot be processed. **Unsigned or incomplete applications cannot be processed.** The following are further instructions on how to complete this application:

New Applicant: Place an (X) in the box next to New Applicant if your firm has **not** previously applied for a Medical Device Manufacturing License at this location while under the current ownership. **This license is non-transferable.** If your firm has changed location, ownership, or both, place an (X) in the box adjacent to the appropriate response and also in the box next to New Applicant. Any questions that do not apply to your company indicate with N/A. **Do not leave any sections blank.**

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.

3.–5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.

6.–8. **Mailing Address:** Enter the full mailing address if different from the facility address.

9. **Facility Operator:** Enter the full name of the person who is responsible for the manufacturing of medical devices at this facility and their title.
10. **Facility Telephone Number:** Enter daytime business telephone number of this facility.
11. **Facility FAX Number:** Enter facility FAX number.
12. **24 Hour Emergency Telephone Number:** Enter telephone number to be called in the event of an emergency.
13. **E-mail Address:** Enter facility or correspondent's email address.
14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
15. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
16. **Correspondent FAX Number:** Enter the daytime business FAX number of the contact person.
17. **Country:** Enter the country where your facility is located if outside of the United States.
18. **FDA CFN or FEI:** Enter your U.S. Food and Drug Administration Central File Number or Federal Establishment ID if known.
19. **Web site:** Enter the web site address for your business if applicable.
20. **Interstate Commerce:** Place an (X) in the boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
21. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
22. **Corporate Name:** Enter corporate name if applicable. Enter the state of incorporation if applicable.
23. **Owner's or Officer's Names:** List the business owners' or officers' names and titles.
24. **Type of Manufacturing Business:** Place an (X) in the box next to the type of manufacturing business conducted at this facility. Check all that apply.
25. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
26. **Intended Device Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
27. **Products Manufactured:** Place an (X) in the box adjacent to each product that applies to the devices manufactured or to be manufactured. If the product being manufactured is not listed, check the box next to unclassified devices.
28. **Classified or Unclassified Devices Manufactured:** For each medical device product, list the federal classification name and classification category (I, II, or III) as listed in 21 CFR, Sections 862 to 892. Refer to the following web sites:
    http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfrv8_00.html
    http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.
    If not known or if thought to be unclassified, please provide your best description for each device. Use additional sheets if necessary.
29. **Manufacturing Processes:** Place an (X) in the column adjacent to any indicated processes to identify if they will be done in-house or contracted-out. Leave line blank if the indicated process will not be used in the manufacture of listed devices. List additional processes or methods as needed herein or on additional sheets, if necessary.
30. **Payment Codes:** Your license fee is based on the application type, products being manufactured and class of devices being manufactured.

Application Type	*Device Classification*	*License Fee*	*Payment Interval*	*Payment Code*
New, Relocation or Ownership Change	I, II, III, Unclassified	$1600	First license only	A
New **** (Special Firms)***	Class I only	$850	First license only	B

**** Special firms are limited to firms that produce medical devices that are classified by the federal regulations as "Class One" and have been exempted from GMP requirements, and firms that only manufacture optical lenses (spectacle lenses).***

31. **License Fee Due:** Enter appropriate fees due.
    a. Enter license fee according to payment codes in #30.
    b. Enter total payment due.
32. **Sign the application, print your name, print your title, and enter the date. All signatures must be original.**

MAKE CHECKS PAYABLE TO: **DEPARTMENT OF HEALTH SERVICES**

MAIL APPLICATION AND CHECK TO:

Regular Mail: California Department of Health Services
Food and Drug Branch - Cashier
MS 7602
P.O. Box 997435
Sacramento, CA 95899-7435

Overnight Mail: California Department of Health Services
Food and Drug Branch - Cashier
1500 Capitol Avenue, MS-7602
Sacramento, CA 95814

If you have any further questions, please contact the Food and Drug Branch, Medical Device Manufacturing Desk at (916) 650-6500 or visit our web site at: http://www.dhs.ca.gov/fdb/.